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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/714,580 | 11/14/2003 | Paul Wentworth | 1361.027US1 | 1792 |

21186 7590 08/01/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

| EXAMINER | |
|---|---|
| HINES, JANA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/714,580 | WENTWORTH ET AL. | |
| | Examiner | Art Unit | |
| | Ja-Na Hines | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *1-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Amendment Entry*

1. The amendment filed May 10, 2006 has been entered. Claim 40 has been amended. Claims 46-47 have been cancelled. Claims 1-30 have been withdrawn from consideration. Claims 40-45 are under consideration in this office action.

### *Priority*

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 40-47 of this application. Applicants submit that US 60/315,906 provide support for the instantly claimed method. However the paragraph presented by applicants is drawn to the production of oxidants. Oxidants are merely substances that oxidize another substance; there is no disclosure of generating ozone. The paragraph also discloses the use of antibody mediated hydrogen peroxide production to increase the local concentration of hydrogen peroxide to combat bacterial infection. Furthermore the paragraph states that the antibody would generate hydrogen peroxide to thereby cause a localized increase in the hydrogen peroxide concentration. The instant claims are not drawn to increasing hydrogen peroxide production; rather the claims are drawn to generating ozone to inhibit the growth of bacteria. There is no disclosure of generating ozone as a way to inhibit the growth of bacteria. There is no disclosure of generating ozone by contacting an

antibody and singlet oxygen to thereby generate ozone, which inhibits the growth of bacteria.

Page 9, lines 12-24 is drawn to therapeutic methods for enhancing the bactericidal effectiveness of a phagocyte in a subject. However it is the examiner's position that the subject matter of page 9 is not commensurate in scope to claims drawn to generating ozone to inhibit the growth of bacteria. Applicants have failed to show a disclosure drawn to generating ozone by contacting an antibody and singlet oxygen to thereby generate ozone, which inhibits the growth of bacteria.

Applicants' point to similar teaching in PCT/US01/29165. However there appears to be no teaching a generating ozone comprising contacting an antibody and singlet oxygen to thereby generate ozone to inhibit the growth of bacterium. Data in 60/426,245 showing that antibodies can kill bacteria does not provide support, since the claims are drawn to the combination of antibodies and singlet oxygen to generate ozone, which would inhibit the bacteria.

The instant claims are drawn to a method of generating ozone to inhibit the growth of a microbe comprising contacting a bacterium with (i) an antibody that can bind to the bacterium and (ii) a source of singlet oxygen. However, none of the provisional applications, for which priority is claimed 60/232/702, 60/235,475, 60/426,245, and 60/315,906 and PCT/US01/29165 teach a method of generating ozone to inhibit the growth of a bacterium comprising the instantly recited steps. Thus, because there was no conception of a method for generating zone to inhibit the growth of a bacterium comprising contacting the bacterium with (i) an antibody that can bind to the bacterium

and (ii) a source of singlet oxygen, the examiner's position is maintained. Applicants' support failed to point to support for: generating ozone; contacting an antibody and singlet oxygen to thereby generate ozone; or using ozone to inhibit the growth of bacterium. Furthermore, applicants' failed to supply support for the source of singlet oxygen not be covalently attached to the antibody or a source of singlet oxygen which would not on its own inhibit the growth of bacteria. Therefore, for the reasons stated above, priority cannot be granted to 60/232/702, 60/235,475, 60/426,245, and 60/315,906 and PCT/US01/29165 since what is now claimed, has not been previously recited in the other applications, contrary to applicants assertions.

***Specification***

3. The substitute specification filed May 8, 2006 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: A substitute specification submitted under this section must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be

shown pursuant to this paragraph. See M.P.E.P. § 1.125. Applicants' failed to supply a substitute specification with markings showing all the changes relative to the immediate prior version of the specification of record. Therefore appropriate clarification is required.

***Withdrawal of Rejections***

4. The following rejections have been in view of applicants' amendments and arguments:

a) The written description rejection over claims 40-47 under 35 U.S.C. 112, first paragraph; and

b) The rejection of claims 40-47 under 35 U.S.C. 112, second paragraph.

***Response to Arguments***

5. Applicant's arguments filed May 8, 2006 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 40-43 under 35 U.S.C. 102(b) as being anticipated by Devanathan et al., is maintained for reasons already of record. The rejection

Devanathan et al., teach a method of generating a reactive oxygen species to inhibit the growth of a bacterium comprising contacting the microbe with (i) an antibody that can bind to the bacterium and (ii) a source of singlet oxygen is a sensitizer molecule just as required by the claims.

Applicants' urge that Devanathan et al., is limited by its teaching of phototoxic photodynamic sensitizer, since the claims recite that the source of singlet oxygen would not on its own inhibit the growth of the bacteria. However it is the examiner's position that Devanathan is not limited by its teaching of phototoxic photodynamic sensitizers. Phototoxic means to render the skin susceptible to damage by light (see the American Heritage Dictionary). Thus the source of singlet oxygen, i.e., the photodynamic sensitizer by itself is not toxic. Rather the combination of light and the sensitizer create the phototoxic characteristic. Devanathan et al., teach that for photodynamic killing of microorganism, the combination of light, oxygen and absorbing dyes called photodynamic sensitizers are essential. Thus the source of singlet oxygen, being the photodynamic sensitizer would not, on its own, inhibit the growth of bacteria contrary to applicants' statement. Therefore the rejection is maintained.

7. The rejection of claims 40-43 and 45 under 35 U.S.C. 102(b) as being anticipated by Berthiaume et al., is maintained for reasons already of record. The rejection was on the grounds that Berthiaume et al., teach a method of generating a reactive oxygen species to inhibit the growth of a bacterium comprising contacting the bacterium with (i)

an antibody or antibody fragment that can bind to the bacterium and (ii) a source of singlet oxygen is a sensitizer molecule just as required by the claims.

Applicants' argue that Berthiaume et al., is limited to using tin(OV) chlorine e, - monoclonal antibody conjugates where the antibody conjugates whereby the antibody acts only as the delivery and has no role in actually killing the bacteria. However, the MPEP section 2123 teaches that prior art is relevant as prior art for all it contains,. For instance, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998). In this case, the Berthiaume et al., reference may be relied upon because it reasonably and explicitly suggest contacting the bacterium with (i) an antibody that can bind to the bacterium and (ii) a source of singlet oxygen is a sensitizer molecule just as required by the claims.

Therefore the fact that Berthiaume et al., do not recite using the antibody to actually kill the bacteria is irrelevant. The claims do not recite that the antibody must actually kill the bacteria. "[T]he discovery of a previously unappreciated property of a

prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Furthermore, an inherent feature need not be recognized at the time of the invention. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). There appears to be no difference in the teaching contacting an antibody and source of singlet oxygen with the bacterium by the prior art. Thus applicants' arguments are not persuasive.

Applicants' urge that there is no disclosure of a composition with an antibody and source of singlet oxygen that would not, own its own, inhibit the growth of the bacteria. However Berthiaume et al., clearly states that photosensitizers are only toxic upon activation by light. Thus, light is needed and the photosensitzer alone would not inhibit the growth of bacteria. Therefore the art teaches photosensitizers as a source of singlet oxygen which on their own, do not inhibit the growth of the bacteria.

8. The rejection of claims 40-42 and 44-47 under 35 U.S.C. 102(b) as being anticipated by Wentworth et al., in light of the Scripps Press Release of November 14, 2002 is maintained for reasons already of record. The rejection is on the grounds that Wentworth et al., teach a method of generating a reactive oxygen species to inhibit the growth of a bacterium comprising contacting the bacterium with (i) an antibody or antibody fragment that can bind to the bacterium and (ii) a source of singlet oxygen is a sensitizer molecule just as required by the claims.

Applicants assert that Wentworth is not prior art because of Applicant's claim for domestic priority under 35 U.S.C. 119(e). However for the reasons stated in the "Priority" section of this response, priority has not been granted to 60/315,906, 60/426,242, and PCT/US01/29165. As previously stated, none of the references teach a method of generating ozone to inhibit the growth of a bacterium comprising the instantly recited steps. Furthermore, there appears to be no conception of a method for generating zone to inhibit the growth of a bacterium comprising contacting the bacterium with (i) an antibody that can bind to the bacterium and (ii) a source of singlet oxygen, as claimed. Therefore, for the reasons stated above, priority cannot be granted to 60/232/702, 60/235,475, 60/426,245, and 60/315,906 and PCT/US01/29165 since what is now claimed, has not been previously recited in the other applications, contrary to applicants assertions.

Therefore, applicants' arguments are not persuasive and the rejection is maintained.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 40-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method of generating a reactive oxygen species to inhibit the growth of a bacterium comprising contacting the bacterium with (i) an antibody or antibody fragment that can bind to the bacterium and (ii) a source of singlet oxygen to thereby generate ozone to inhibit the growth of a bacterium, wherein the source of singlet oxygen is not covalently attached to the antibody and the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria.

Applicant did not point to support in the specification for the instantly claimed method. Applicants points to Example 3 at pages 85-90, however there is no teaching of a source of singlet oxygen that is not covalently attached to the antibody. The pages do teach the generation of ozone using antibodies and various sources of singlet oxygen's; however there is no discussion of covalent bonds. Therefore, applicant failed to

specifically point to support for a source of singlet oxygen is not covalently attached to the antibody. Accordingly, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for a method of generating a reactive oxygen species to inhibit the growth of a bacterium comprising contacting the bacterium with (i) an antibody or antibody fragment that can bind to the bacterium and (ii) a source of singlet oxygen to thereby generate ozone to inhibit the growth of a bacterium, wherein the source of singlet oxygen is not covalently attached to the antibody and the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria as recited by the amended claim. Therefore, the claims incorporate new matter and are accordingly rejected.

***Conclusion***

10. No claims allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
July 18, 2006

ROBERT A. ZEMAN
PRIMARY EXAMINER